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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,644	01/08/2002	Jacques F. Banchereau	AGT.10006NP	7691

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EXAMINER
CHANDRA, GYAN

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
07/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/042,644	BANCHEREAU ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/13/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52,69-77,80-82,84-92 and 96-99* is/are pending in the application.

4a) Of the above claim(s) *1-52,69-77,82 and 84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80-81, 85-92 and 96-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/24/2006; 6/13/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/13/2007 has been entered.

Status of Application, Amendments, And/Or Claims

The cancellation of claims 83 and 94-95 and the addition of new claims 94-96 have been made of record.

Claims 1-52, 69-77, 80-82, 84-92 and 96-99 are pending.

Claims 1-52, 69-77, 82 and 84 remain withdrawn.

Claims 80-81, 85-92 and 96-99 are examined on the merit to the extent that they read on the elected species psoriasis, and an antibody as the interferon antagonist.

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 80-81, 85-92 and 96 remain rejected under 35 U.S.C. 102(b) for the reasons of record in the previous Office Action mailed on 12/14/2006, and newly added claims 97-99 are rejected under 35 U.S.C. 102(b) as being anticipated by Skurkovich et al (US Patent No. 5,888,511).

Claims 80-81, 85-92 and 96-99 are broadly drawn to a method of treating an autoimmune disease in a subject comprising administering a composition consisting of one or more antibodies consisting of one or more humanized, monoclonal anti-IFN-α antibodies or antigen-binding fragments thereof and a diluent, a preservative, a solubilizer, an emulsifier, an adjuvant, a carrier, a buffer, a pharmaceutical additive, a detergent, an anti-oxidant, a bulking substance, a tonicity modifier, a flavoring agent, a lubricant, a suspending agent, a filler, a glidant, a compression aid, a binder, a tablet-disintegrating agent, an encapsulating material, a sweetener, a thickening agent, a color, a viscosity regulator, a stabilizer, an osmo-regulator, a pharmaceutically acceptable propellent, a flavorant, a dye, a coating, or a combination of any thereof, wherein said autoimmune disease is not rheumatoid arthritis, Acquired Immune Deficiency Syndrome (AIDS), or diabetes, and wherein no neutralizing anti-TNF antibodies are used in the method, wherein one or more anti- IFN-α antibodies or antigen binding fragment are administered at a dosage of about 1 to about 10 fold molar excess of interferon, wherein one or more anti- IFN-α antibodies or antigen binding fragments thereof reduce binding of a type I interferon to its receptor, wherein one or more anti- IFN-α antibodies or antigen binding fragments thereof reduce interferon-dependent signal transduction, wherein one or more anti- IFN-α antibodies or antigen binding fragments thereof reduce interferon serum levels, wherein one or more anti- IFN-α antibodies or antigen binding fragments thereof reduce interferon secretion from cell as measured by interferon receptor binding assay, wherein one or more anti- IFN-α antibodies or antigen binding fragments thereof reduce bioavailability of interferon in serum as measured by an interferon receptor binding assay, wherein one or more anti- IFN-α antibodies or antigen binding fragments thereof reduce development of cells which produce type I interferon in the subject as measured by a monocyte differentiation assay, and wherein the autoimmune diseases is psoriasis.

Applicants argue (page 13 of Response) that (i) the amended of claims to recite "**no neutralizing anti-TNF antibodies are used in the method**" excludes the use of anti-TNF antibody as taught by

Skurkovich et al. Applicants argue that (ii) the prior art Skurkovich et al does not disclose effective methods comprising the administration of a composition consisting of humanized or human monoclonal antibodies (or antigen binding fragment thereof) against IFN-α alone, wherein no neutralizing anti-TNF antibodies are used in the method. Applicants argue that (iii) Skurkovich et al. teach using multiple therapeutic agents for effective treatment of autoimmune diseases.

Applicants arguments have been considered but is not persuasive because Skurkovich et al clearly define the term "antibody" which includes monoclonal antibody, polyclonal antibodies, humanized forms of the monoclonal antibodies, chimeric antibodies, as well as biologically active fragments, functional equivalents, derivatives, or allelic or species variants thereof (column 15, lines 2-8). Skurkovich et al teach using a pharmaceutical composition comprising suitable carriers or excipients well known in the art (column 19, lines 3+). The skill of preparing pharmaceutical composition wherein said composition comprises diluents, carriers or buffer is very high (de Lange et al., US Patent No. 5,859,183, col. 39-40).

Applicant's arguments that the claims now recite "consisting of" has been fully considered but they are not persuasive because Skurkovich et al. contemplate administering a single antibody intramuscularly or intravenously in a patient having an autoimmune disease (column 15, lines 58+), which meets the limitation "consisting of." Further, de Lange is applied to support the skills of art, and not as a prior art. Skurkovich et al. define a **patient population** as patients in need of treatment with an autoimmune disease inhibitor when the patient is suffering from an autoimmune disease (column 11, lines 23+). Skurkovich et al teach patients suffering from autoimmune diseases Addison's disease, Crohn's disease, psoriasis Graves' disease and many others (see Table 1). Skurkovich et al contemplate treating various autoimmune diseases by blocking, neutralizing or inhibiting different types of interferons (column 7, lines 40+ and column 8, lines 22+). Skurkovich et al teach that primary indicator of each autoimmune disease is the hyperproduction of IFN-α (column 8, lines 32-33). **Skurkovich et al emphasize treating patients with autoimmune diseases using substantially purified monoclonal antibody produced in**

human hybridoma (column 15, lines 58+). They teach that humanized monoclonal antibody could be produced using one of the methods known in the art such as CDR grafting or chimerization (column 15, lines 61+). Although Skurkovich (column 4, lines 9-24) states that the autoimmune diseases are complex and multiple cytokines may play role and therefore, for effective treatment, a combination approach would work better, Skurkovich's teach that a single antibody against IFN-alpha could treat any autoimmune disease as disclosed in Table 1. Further, Skurkovich et al contemplate treating autoimmune disease in a patient comprising alone or in conjunction with administering to the patient an effective amount of one or more anti- IFN-α(column 6, lines 16+). Therefore, Skurkovich's teachings do not necessarily negate for the use of single antibody for treating an autoimmune disease. Further, because Skurkovich et al teach to using a single antibody to treat an autoimmune disease, Skurkovich's teaching does not contemplate including a neutralizing anti-TNF antibody.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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11 March 2007
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/Robert S. Landsman/
Primary Examiner, Art Unit 1647